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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/062,710	02/05/2002	Frank Q. Li	3781-001-27	3114

7590 04/22/2005

Supervisor, Patent Prosecution Services
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EXAMINER	
DIBRINO, MARIANNE NMN	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 04/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/062,710	LI ET AL.	
	Examiner	Art Unit	
	DiBrino Marianne	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *1-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/~~Mail Date~~ Filed *3/29/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

1. Applicant's amendment filed 1/21/05 is acknowledged and has been entered.

2. Applicant is reminded of Applicant's election of Group III with traverse (13-14) in Applicant's response filed 5/20/04.

Claims 13 and 14, and newly added claims 15-21 are presently being examined.

3. The amendment filed 1/21/05 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The deletion of the prediction algorithm for protesosomal cleavages at the last line of Applicant's amendment to the specification at the third paragraph at page 43, line 10, because there is no disclosure of the prediction algorithm any longer.

Applicant may reinsert the deleted information if it is no longer a hyperlink, such as for example, "see the NetChop site at" or "see the Proprac site at" ... and delete the http://www." portion.

Applicant is required to cancel the new matter in the reply to this Office Action.

The following are new grounds of rejection necessitated by Applicant's amendment filed 1/21/05.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendatory material not supported by the disclosure as originally filed is as follows:

(a) "at least 50,000 daltons" (claims 13 and 14);
(b) "at least 250,000 daltons" (claim 19);
(c) "at least 500,000 daltons" (claim 20); and
(d) "at least 750,000 daltons" (claim 21).

The Examiner notes that Applicant does not point to support in the instant disclosure for the claim amendments.

5. For the purpose of prior art rejections, the filing date of the instant claims 13-21 is deemed to be the filing date of the instant application, i.e., 2/5/02, as the provisional application serial no. 60/310,498 does not support the claimed limitations of the instant application, i.e., the limitations "particle-free" and the limitations enunciated at item #4 (a)-(d) supra.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the. . .claimed subject matter", Vas-Cath, Inc. V. Mahurkar, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the Applicant had possession at the time of invention of the claimed invention.

Applicant has not provided adequate written description for "polypeptide consisting of a B cell epitope, wherein the B cell epitope is recognized by an MHC molecule of the mammal" recited in instant claim 16 because the claims encompass a polypeptide that consists of a B cell epitope that is recognized by an MHC class II molecule of a mammal.

The art recognizes that recognition of a B cell epitope is non-MHC restricted, whereas recognition of a Th cell epitope that provides help for B cell production of antibody is MHC class II restricted.

The instant specification on page 40 at lines 7-10 discloses "The term "B cell epitope" refers to a portion of an antigen, typically a peptide, capable of binding to an antigen binding site of an immunoglobulin and therefore capable of stimulating a humoral response without presentation in an MHC molecule."

In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein.

8. Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not disclose how to make and use the instant invention The composition recited in claim 16 comprising an HA-polymer analogue conjugated to a second "polypeptide consisting of a B cell epitope, wherein the B cell epitope is recognized by an MHC molecule of the mammal". The state of the art is such that it is unpredictable in the absence of appropriate evidence whether the claimed composition can be made and used because the claim encompasses a polypeptide that consists of a B cell epitope that is recognized by an MHC class II molecule of a mammal. The specification discloses no working examples with regards to such a B cell epitope that is recognized by an MHC class II molecule of a mammal.

The instant specification on page 40 at lines 7-10 discloses "The term "B cell epitope" refers to a portion of an antigen, typically a peptide, capable of binding to an antigen binding site of an immunoglobulin and therefore capable of stimulating a humoral response without presentation in an MHC molecule."

The art recognizes that recognition of a B cell epitope is non-MHC restricted, whereas recognition of a Th cell epitope that provides help for B cell production of antibody is MHC class II restricted. Evidentiary reference Male teaches that Th cells recognize antigen, i.e., epitopes, in association with MHC class II molecules, and CTLs recognize antigen, i.e., epitopes, in association with MHC class I molecules (pages 3 and 4), and that B cell receptor is antibody which recognizes nominal antigen (pages 3, 6, 19 and 23).

There is insufficient guidance in the specification as to how to make and/or use instant invention. Undue experimentation would be required of one skilled in the art to practice the instant invention. See In re Wands 8 USPQ2d 1400 (CAFC 1988).

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 is indefinite in the recitation of " a B cell epitope, wherein the B cell epitope is recognized by an MHC molecule of the mammal" because it is not clear what is meant, i.e., recognition of a B cell epitope is non-MHC restricted, whereas recognition of a Th cell epitope that provides help for B cell production of antibody is MHC class II restricted. It is suggested that Applicant amend said claim to recited "a Th cell epitope, wherein the Th cell epitope is recognized by an MHC molecule of the mammal" if that is what is meant.

The instant specification on page 40 at lines 7-10 discloses "The term "B cell epitope" refers to a portion of an antigen, typically a peptide, capable of binding to an antigen binding site of an immunoglobulin and therefore capable of stimulating a humoral response without presentation in an MHC molecule."

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

As pertains to the inclusion of claim 16 in the following rejections, B cell epitope recognized by MHC class II recited in instant claim 16 is being interpreted to mean aTh epitope.

12. Claims 13-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/62895 A2 in view of U.S. Patent No. 5,993,819, U.S. Patent No. 5,662,907 and Noble et al (J. Exp. Med. 183: 2373-2378, 1996).

WO 01/62895 A2 teaches a polymer that may be a hyaluronic acid (HA) polymer attached to one or more agents that ligate a cell surface moiety of at least a population of T cells and stimulates said at least a population of T cells, B cells or dendritic cells, wherein the said one or more agents may be a peptide that binds to an MHC molecule (especially page 3 at line 10 through page 4 at line 4page 18 at line 15 through page19 at line 27, page 38 at lines 10-27, and claims 1, 3, 5-7, 15, 23 and 24).

WO 01/62895 A2 does not teach the molecular weight of the HA polymer, nor wherein the MHC peptide(s) is a T cell epitope(s) that is recognized by MHC class I (i.e., a CTL epitope), nor wherein the T cell epitope peptide(s) is conjugated to an epitope peptide(s) that is recognized by MHC class II (i.e., a Th epitope), i.e., they bind to either MHC class I or to MHC class II.

U.S. Patent No. 5,993,819 discloses T (i.e., CTL) cell epitope peptides covalently linked to carriers for vaccination in humans and other mammals, and that the peptides may also be linked to Th or B cell epitopes, and administered along with a pharmaceutically acceptable adjuvant, and may be conjugated to other carrier molecules more immunogenic than tetanus toxoid. U.S. Patent No. 5,993,819 discloses examples of HIV epitope peptides (especially abstract, column 3 at lines 20-28 and 40-46, column 5 at lines 2-6 and 17-29, column 7 at lines 16-32, and table XXVII).

U.S. Patent No. 5,662,907 discloses that one or multiple class I or class II MHC binding peptides, or both, may be used in vaccines that further comprise an adjuvant. U.S. Patent No. 5,662,907 discloses that class II binding peptides may be included that stimulate Th lymphocytes (i.e., they bind to MHC class II). U.S. Patent No. 5,662,907 discloses that the peptides may be linked to carriers and to other peptides to form polymers (see entire document).

Noble et al teach using purified 400,000 dalton HA to activate macrophages, the said macrophages being an essential cellular component of the inflammatory response as they release proteases, lipid mediators, cytokines and growth factors. Noble et al teach that the larger native molecule HA does not possess similar activity (see entire article, especially page 2373, page 2375, and discussion section on page 2377).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have used the MHC binding peptides disclosed by U.S. Patent No. 5,993,819 and U.S. Patent No. 5,662,907 and the 400,000 dalton HA taught by Noble et al in the MHC binding peptide-HA polymer taught by WO 01/62895 A2.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this in order to make a peptide-HA polymer conjugate that would be capable of stimulating at least a population of T cells, dendritic cells or B cells as disclosed by WO 01/62895 A2 by using CTL and Th epitope peptides that bind to class I MHC or to class II MHC, respectively, as disclosed for peptide/carrier conjugates disclosed by U.S. Patent No. 5,993,819 and U.S. Patent No. 5,662,907, and further by using an HA polymer of the molecular weight taught by Noble et al that activates macrophages, i.e., the HA stimulates antigen presenting cells (APC) that possess class I MHC or class II molecules, the said APC being stimulated to release cytokines and growth factors.

With regard to the recitation of "article-free" hyaluronic acid polymer analogue recited in instant base claims 13 and 14, the claimed hyaluronic acid polymer appears to be the same or similar to the HA polymer of the prior art absent a showing of unobvious differences. Since the Patent Office does not have the facilities for examining and comparing the composition of the instant invention to those of the prior art, the burden is on Applicant to show an unobvious distinction between the antibody of the instant invention and that of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

13. Claims 13-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/62895 A2 in view of U.S. Patent No. 5,993,819, U.S. Patent No. 5,662,907 and Rafi et al (Blood 89(8): 2901-2908, 1997) and admissions in the specification on page 24 at lines 8-14.

WO 01/62895 A2 teaches a polymer that may be a hyaluronic acid (HA) polymer attached to one or more agents that ligate a cell surface moiety of at least a population of T cells and stimulates said at least a population of T cells, B cells or dendritic cells, wherein the said one or more agents may be a peptide that binds to an MHC molecule (especially page 3 at line 10 through page 4 at line 4page 18 at line 15 through page19 at line 27, page 38 at lines 10-27, and claims 1, 3, 5-7, 15, 23 and 24).

WO 01/62895 A2 does not teach the molecular weight of the HA polymer, nor wherein the MHC peptide(s) is a T cell epitope(s) that is recognized by MHC class I (i.e., a CTL epitope), nor wherein the T cell epitope peptide(s) is conjugated to an epitope peptide(s) that is recognized by MHC class II (i.e., a Th epitope), i.e., they bind to either MHC class I or to MHC class II.

U.S. Patent No. 5,993,819 discloses T (i.e., CTL) cell epitope peptides covalently linked to carriers for vaccination in humans and other mammals, and that the peptides may also be linked to Th (or B cell) epitopes, and administered along with a pharmaceutically acceptable adjuvant, and may be conjugated to other carrier molecules more immunogenic than tetanus toxoid. U.S. Patent No. 5,993,819 discloses examples of

HIV epitope peptides (especially abstract, column 3 at lines 20-28 and 40-46, column 5 at lines 2-6 and 17-29, column 7 at lines 16-32, and table XXVII).

U.S. Patent No. 5,662,907 discloses that one or multiple class I or class II MHC binding peptides, or both, may be used in vaccines that further comprise an adjuvant. U.S. Patent No. 5,662,907 discloses that class II binding peptides may be included that stimulate Th lymphocytes (i.e., they bind to MHC class II). U.S. Patent No. 5,662,907 discloses that the peptides may be linked to carriers and to other peptides to form polymers (see entire document).

Rafi et al teach that soluble HA was shown to bind CD44 on activated T cells and was demonstrated to act as a costimulatory ligand for CD44 in the activation of human T cell effector function, and that soluble HA could also stimulate B lymphocytes in mice in vivo. With respect to the limitation "particle-free hyaluronic acid" recited in instant base claims 13 and 14, Rafi et al teach use of soluble HA in their B cell differentiation assay (especially Materials and Methods section on page 2902).

The admissions in the specification on page 24 at lines 8-14 are that HA has molecular weight between 600,000 to 1,000,000 daltons.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have used the HA taught by Rafi et al and the MHC class I and class II binding peptides disclosed by U.S. Patent No. 5,993,819 or U.S. Patent No. 5,662,907 in the invention taught by WO 01/62895 A2.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this in order to make a polymer conjugate as taught by WO 01/62895 A2 that would be capable of activating T cell and B cell function to the class I and class II MHC binding peptides disclosed by U.S. Patent No. 5,993,819 and U.S. Patent No. 5,662,907 by further using the HA taught by Rafi et al that activates T and B lymphocytes.

The motivation to combine can arise from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Section MPEP 2144.07.

14. Claims 13-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,063,370 (IDS reference) in view of U.S. Patent No. 5,593,819 and U.S. Patent No. 5,662,907 and admissions in the specification on pages 36-37.

U.S. Patent No. 6,063,370 discloses insulin or other proteins or peptides covalently linked to linear polymers such as polymers of hyaluronic acid (HA) for administration to humans in conjunction with a pharmaceutical carrier. U.S. Patent No. 6,063,370 further discloses that the polymer has a molecular weight of about 50,000 daltons (especially column 7 at lines 32-48). U.S. Patent No. 6,063,370 further discloses that GAG carriers have been shown to be highly potent, selective inhibitors of HIV replication, but that they are unsuitable for administration because they have anticoagulant properties and are heterogeneous and difficult to reproduce. U.S. Patent No. 6,063,370 discloses that polymers of the invention such as HA polymers provide the benefits of GAG, but avoid the disadvantages associated with long-term administration of a GAG compound.

U.S. Patent No. 6,063,370 does not disclose wherein the HA is conjugated to a peptide(s) that binds to class I MHC and further conjugated to a peptide(s) that binds to class II MCH, i.e., T cell (CTL) and Th epitope(s), respectively.

U.S. Patent No. 5,993,819 discloses T (i.e., CTL) cell epitope peptides covalently linked to carriers for vaccination in humans and other mammals, and that the peptides may also be linked to Th (or B cell) epitopes, and administered along with a pharmaceutically acceptable adjuvant. U.S. Patent No. 5,993,819 discloses examples of HIV epitope peptides (especially abstract, column 3 at lines 20-28 and 40-46, column 5 at lines 2-6 and 17-29, column 7 at lines 16-32, and table XXVII).

U.S. Patent No. 5,662,907 discloses that one or multiple class I or class II MHC binding peptides, or both, may be used in vaccines that further comprise an adjuvant. U.S. Patent No. 5,662,907 discloses that class II binding peptides may be included that stimulate Th lymphocytes (i.e., they bind to MHC class II). U.S. Patent No. 5,662,907 discloses that the peptides may be linked to carriers and to other peptides to form polymers (see entire document).

The admissions in the specification on pages 36-37 are that "particle free" is a polymer preparation that is non-crosslinked, i.e., linear.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have used the class I MHC and the class II MHC binding peptides disclosed by U.S. Patent No. 5,662,907 or by U.S. Patent No. 5,993,819 as the peptides in the peptide-HA conjugates disclosed by U.S. Patent No. 6,063,370.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this because U.S. Patent No. 6,063,370 discloses that linear HA polymer is a preferred drug delivery carrier for peptides as well as other drugs, and

U.S. Patent No. 5,993,819 discloses conjugation of Th and CTL epitopes to carrier molecules, as does U.S. Patent No. 5,662,907. In addition, particularly wherein the HIV epitope peptides disclosed by U.S. Patent No. 5,993,819 were being administered, one of ordinary skill in the art at the time the invention was made would have been motivated to do this because U.S. Patent No. 6,063,370 discloses that a benefit of using the polymers disclosed by U.S. Patent No. 6,063,370 include selective inhibition of HIV replication.

15. Claims 13-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/05434 A2 (25 January 2001) in view of U.S. Patent No. 5,993,819 and U.S. Patent No. 5,662,907.

WO 01/05434 A2 teaches use of hyaluronic acid (HA)-protein, polypeptide or peptide conjugates/pharmaceutical compositions thereof having the advantage of longer sustained blood levels of administered proteins, polypeptides or peptides in the conjugates with HA. WO 01/05434 A2 teaches that the HA may be 80,000 daltons (especially pages 1, 3-5, page 8 at lines 12-15).

WO 01/05434 A2 does not teach wherein the peptide(s) conjugated to HA are MHC class I or MHC class II binding epitope peptide(s).

U.S. Patent No. 5,993,819 discloses T (i.e., CTL) cell epitope peptides covalently linked to carriers for vaccination in humans and other mammals, and that the peptides may also be linked to Th (or B cell) epitopes, and administered along with a pharmaceutically acceptable adjuvant. U.S. Patent No. 5,993,819 discloses examples of HIV epitope peptides (especially abstract, column 3 at lines 20-28 and 40-46, column 5 at lines 2-6 and 17-29, column 7 at lines 16-32, and table XXVII).

U.S. Patent No. 5,662,907 discloses that one or multiple class I or class II MHC binding peptides, or both, may be used in vaccines that further comprise an adjuvant. U.S. Patent No. 5,662,907 discloses that class II binding peptides may be included that stimulate Th lymphocytes (i.e., they bind to MHC class II). U.S. Patent No. 5,662,907 discloses that the peptides may be linked to carriers and to other peptides to form polymers (see entire document).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have used the MHC class I or MHC class II epitope peptides disclosed by U.S. Patent No. 5,993,819 or U.S. Patent No. 5,662,907 conjugated to HA as taught by WO 01/05434 A2 for administration pharmaceutically.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this in order to extend the blood levels as taught by WO 01/05434 A2 for the epitope peptides disclosed by U.S. Patent No. 5,993,819 and U.S. Patent No. 5,662,907, particularly since the latter two patents disclose use of carriers for the peptides.

With regard to the recitation of "article-free" hyaluronic acid polymer analogue recited in instant base claims 13 and 14, the claimed hyaluronic acid polymer appears to be the same or similar to the HA polymer of the prior art absent a showing of unobvious differences. Since the Patent Office does not have the facilities for examining and comparing the composition of the instant invention to those of the prior art, the burden is on Applicant to show an unobvious distinction between the antibody of the instant invention and that of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

16. No claim is allowed.

17. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware of in the specification.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Y. Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marianne DiBrino, Ph.D.
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Group 1640
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April 12, 2005